A. Sources Sought Notice: **HHS-NIH-NHLBI-SBSS-HB-2018-01AB (FBO) / HHSN26818HB00001 (FedConnect)**

B. Title: Innovative Clinical Trials Resource (ICTR)

C. This is a Small Business Sources Sought Notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified business sources; and (2) their size classification relative to the **North American Industry Classification System (NAICS) code 541690** for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method. All capability Statements sent in response to this SOURCES SOUGHT notice must be submitted electronically via Fedconnect web portal (www.fedconnect.net). It must be in MS Word or Adobe Portable Document Format (PDF), by **February 1st, 2017, 9:00 AM**, EASTERN TIME under Solicitation Number: **HHS-NIH-NHLBI-SBSS-HB-2018-01AB (FBO)** FAXES ARE NOT ACCEPTED

D. Information:

1. Background

Clinical trials are a key strategy used by the National Heart, Lung, and Blood Institute (NHLBI) to improve the understanding of the clinical mechanisms of disease and to improve prevention, diagnosis, and treatment of heart, lung, blood, and sleep disorders. Clinical trials also represent a significant investment of human and material resources. Effective planning, oversight, and high standards for the safe, timely, and efficient conduct of clinical trials are integral to maximizing their scientific impact and return on investment, as well as to maintaining public trust in the clinical trials enterprise.

The recently revised NHLBI single-site (PAR-16-405) and multi-site phase II and beyond (PAR-16-300 (CCC), PAR-16-301 (DCC)) clinical trial Funding Opportunities Announcements (FOAs) are designed to enhance the selection, administration, conduct, and oversight of NHLBI clinical trials through the identification, inclusion, and application of well-defined critical performance milestones. Applications to these FOAs require the inclusion of a clinical trial design and statistical monitoring and analysis plan. However, as noted in the 2001 IOM Report on Small Clinical Trials, clinical trials conducted in limited populations may not be able to use traditional clinical trial designs to achieve adequate statistical power and that designing and planning trials using new **i**nnovative statistical design and analysis plans requires specific expertise that may be difficult to locate and access. Scientific areas identified across NHLBI, in which such trials might be required include, but are not limited to, studies of rare diseases and/or therapeutics, studies in sub-populations of more common diseases, e.g. precision medicine approaches to common diseases, and late-stage implementation research.

To meet this challenge, the NHLBI has developed the Catalyzing Innovation in Late Phase Clinical Trial Design and Statistical Analysis Plans Initiative. The initiative aims to support methodological innovation in clinical trial design and analysis by establishing an Innovative Clinical Trials Resource (ICTR). The ICTR will serve as a consultative clinical

trial methodology resource to eligible investigators with important **clinical** or implementation trials that require i) non-standard rather than traditional designs because randomized controlled approaches to the study questions are inadequate, limited, or suboptimal; and ii) the incorporation of novel/innovative statistical analysis techniques. Investigators seeking access to the ICTR services will submit applications to either a U34 (NOT-HL-16-473) or XO1 (NOT-HL-16-474) NHLBI FOA. These FOAs propose to support trial design and analysis planning activities for late phase clinical trials (Phase II and beyond) by providing eligible investigators with access to the ICTR. Successful applicants will use the consultative services of the ICTR to further develop and finalize their study protocol and analysis plan.

In addition, the ICTR will develop and provide a web-based education program in novel clinical trial design and analysis. This program will target the NHLBI clinical trials community and include a public website with educational materials and webinars.

2. Purpose and Objectives

The purpose of this contract is to establish an Innovative Clinical Trials Resource (ICTR) to support the NHLBI Catalyzing Innovation in Late Phase Clinical Trial Design and Statistical Analysis Plans Initiative. The objective of the ICTR is to provide the infrastructure and expertise necessary to provide consultative and education services required by the Initiative. The Government intends to negotiate one (1) cost-reimbursement Indefinite Delivery/Indefinite Quantity contract to address the Government's requirements.

The ICTR infrastructure will include providing a web-based communication platform with a secure private and public environment. The private environment will facilitate communication between the ICTR, NHLBI and investigators. The public environment will facilitate training investigators on innovative clinical trial design and analysis. The consultative services will require broad statistical expertise in innovative clinical trial design and analysis for studies on heart, lung, blood and sleep disorders, and expertise in clinical trial implementation and recruitment. The statistical services will include assisting investigators with developing the trial design and the protocol analysis plan and finalizing the trial's clinical protocol. The implementation services will include providing guidance on regulatory issues related to the proposed study and identifying and establishing collaborations with patient advocacy organizations, professional societies and other organizations critical to study implementation and recruitment. Assistance related to data management and study coordination will not be provided. The education services will include developing a training program on the application of non-traditional clinical trial design and analysis relevant to the NHLBI research community. The program will include developing and maintaining materials for the public facing website and arranging and hosting two education webinars each contract year.

Applicants to the U34 and XO1 FOAs will propose a late phase clinical trial (Phase II and beyond) to address an important clinical or implementation trials that require i) non-standard rather than traditional designs because randomized controlled approaches to the study questions are inadequate, limited, or suboptimal; and ii) the incorporation of

novel/innovative statistical analysis techniques. Successful applications will include a draft protocol, a clinically experienced team that includes a dedicated biostatistician and an institutional clinical trials environment that can support finalization and implementation of the protocol. It is anticipated that up to five U34 and five XO1 applicants will be eligible to start receiving ICTR services within the first six months of the contract award and that an additional five U34 and five XO1 applicants will be eligible to start receiving services in the second six months of contract award. The U34 and XO1 grants will be awarded for a 12-month period.

3. Project Requirements

The Contractor will provide the appropriate facilities and equipment, and the administrative, regulatory, IT, trial design and statistical expertise necessary to serve as a consultative clinical trial methodology resource to NHLBI supported investigators planning important clinical or implementation trials that require: i) non-standard rather than traditional designs because randomized controlled approaches to the study questions are inadequate, limited, or suboptimal; and ii) the incorporation of novel/innovative statistical analysis techniques. The Contractor will not support consultative services for traditional randomized clinical trials, the planning of early phase trials or clinical study data coordinating services. It is anticipated that resources will be provided to up to 20 NHLBI supported groups.

Specifically, the Contractor will be required to:

A. Provide up to 12 months of consultative services in innovative clinical trial design and novel/innovative statistical analysis to investigators planning important clinical or implementation trials that require: i) non-standard rather than traditional designs because randomized controlled approaches to the study questions are inadequate, limited, or suboptimal; and ii) the incorporation of novel/innovative statistical analysis techniques;

B. Provide consultative assistance in clinical protocol finalization and trial implementation strategies, including collaborations with patient advocacy organizations professional societies, and other organizations critical to trial implementation and recruitment;

C. Provide guidance on regulatory issues related to innovative late phase clinical trials;

D. Establish, enhance and maintain a secure, robust, validated web-based communication platform that can be customized to meet the needs of the program;

E. Provide a private web-based communication platform within one month (30 days) of contract award and a public web-based communication platform within three months (90 days) of contract award. The platform and all web-based resources will be compliant with all Federal and State regulation requirements;

F. Have the ability to adjust the contract staff expertise and effort to meet the alternative trial design and analysis plan needs of the program;

G. Communicate via teleconference call on a regular schedule with the NHLBI program team and provide agendas and minutes in a timely manner;

H. Communicate on a regular schedule over a twelve-month period with the NHLBI approved investigator groups;

I. Provide staff with the appropriate expertise to develop and implement a proven effective web-based education program on non-traditional clinical trial design and initiate the program within three months (90 days) of contract award;

J. Collaborate with other NHLBI funded programs to leverage existing resources.

K. Organize and host two educational webinars each contract year as part of the education program; and

L. Ensure an orderly transition at contract termination.

Period of Performance

The Government intends to negotiate one (1) cost-reimbursement Indefinite Delivery/Indefinite Quantity contract for a period of two years with an approximate award date of May 1, 2018.

Place of performance

National Institutes of Health-NHLBI
6701 Rockledge Drive
Bethesda, MD 20817

4. Capability Statement

Interested parties are expected to review this notice to familiarize itself with the requirements of this project. Failure to do so will be at your firm's own risk. The following information shall be included in the capability statement:

a. A general overview of the respondents' opinions about the difficulty and /or feasibility of the potential requirement, and any information regarding innovative ideas or concepts.

b. Information as needed in sufficient details of the respondents' (a) staff expertise, including their availability, experience, and formal and other training; (b) current in-house capability and capacity to perform the work; (c) prior completed projects of similar nature; (d) corporate experience and management capability; and (e) examples of prior completed Government contracts, references, and other related information.

c. The respondents' DUNS number, organization name, address, point of contact,

and size and type of business (e.g., 8(a), HUBZONE, etc.) pursuant to the North American Industry Classification System (NAICS) code: 541690, Other Scientific and Technical Consulting Services, Small Business Size, $15 Million.

d. Any other information that may be helpful in developing or finalizing the requirements of the potential acquisition.

e. The capability statement shall not exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in single-space and using a 12-point font size minimum, in either Microsoft Word or Adobe Portable Document Format (PDF), with 8-1/2 by 11-inch paper size, and 1-inch top, bottom, left and right margins.

f. All proprietary information should be marked as such. Statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address). Responses will be reviewed only by NIH personnel and will be held in a confidential manner.

5. Closing Statement

Interested parties shall submit capability statements via the FedConnect web portal (www.fedconnect.net) and reference Sources Sought Number **HHSN26818HB00001**. The due date for receipt of statements is **February 1st, 2017 by 9:00 AM Eastern Time**. Vendors can register with FedConnect at https://www.fedconnect.net/FedConnect/default.htm. Please note that FedConnect is used by multiple federal agencies and therefore FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect Ready, Set, Go! Guide at https://www.fedconnect.net/fedconnect/Marketing/Documents/FedConnect_Ready_Set_Go.pdf. For assistance in registering or for other FedConnect technical questions please call the FedConnect Help Desk at (800) 899-6665 or email at support@fedconnect.net.

This Sources Sought Notice is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Heart, Lung, and Blood Institute (NHLBI).

The NHLBI does not intend to award a contract on the basis of responses nor otherwise pay for the preparation of any information submitted. As a result of this notice, the NHLBI may issue a Request for Quote (RFQ).

THERE IS NO SOLICITATION AVAILABLE AT THIS TIME. However, should such a requirement materialize, no basis for claims against NHLBI shall arise as a result of a response to this notice or the NHLBI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

Disclaimer and Important Notes: This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.